UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

FEDERAL TRADE COMMISSION and

THE PEOPLE OF THE STATE OF NEW YORK, by LETITIA JAMES, Attorney General of the State of New York,

Plaintiffs,

v.

QUINCY BIOSCIENCE HOLDING COMPANY, INC., a corporation;

QUINCY BIOSCIENCE, LLC, a limited liability company;

PREVAGEN, INC., a corporation d/b/a/ SUGAR RIVER SUPPLEMENTS;

QUINCY BIOSCIENCE MANUFACTURING, LLC, a limited liability company; and

MARK UNDERWOOD, individually and as an officer of QUINCY BIOSCIENCE HOLDING COMPANY, INC., QUINCY BIOSCIENCE, LLC, and PREVAGEN, INC.,

Defendants.

Case No. 1:17-cv-00124-LLS

MEMORANDUM OF LAW IN SUPPORT OF
DEFENDANTS' RENEWED MOTION FOR JUDGMENT AS A MATTER OF LAW

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Defendants Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC, Prevagen, Inc., and Quincy Bioscience Manufacturing, LLC (collectively, "Quincy" or "Defendants") move pursuant to Federal Rule of Civil Procedure 50(b) for entry of judgment as a matter of law in their favor on all counts.

I. PRELIMINARY STATEMENT

After ten days of trial, the New York Attorney General's Office ("NYAG") failed to satisfy its burden of persuasion that six out of the eight alleged marketing claims for Prevagen® being challenged at trial (the "Challenged Claims") mislead any consumer. Further, the NYAG failed to prove that Defendants' scientific substantiation did not satisfy the competent and reliable scientific evidence standard. It is no wonder that the jury found that the primary Challenged Claims (six out of eight of the Challenged Claims) were not materially misleading and therefore did not violate New York's General Business Law ("GBL"). In light of the NYAG's myriad failures of proof, this Court should grant judgment as a matter of law to Defendants on all counts.

First, as to the only two Challenged Claims for which the jury found the NYAG satisfied its burden of persuasion (i.e., "clinically shown to reduce memory problems associated with aging" and "reduce memory problems associated with aging," collectively the "Jury Verdict Claims") there is absolutely no evidence in the trial record that the Defendants ever actually made these Challenged Claims to consumers. On this basis alone, the Court should grant Defendants judgment as a matter of law. However, even generously assuming that the jury found the Jury Verdict Claims to be implied from other evidentiary materials, the NYAG was required to—but did not—introduce extrinsic evidence such as consumer perception evidence demonstrating that consumers understand the advertising and labeling to say or suggest that Prevagen is "clinically shown to reduce memory problems associated with aging" and "reduces memory problems associated with aging." In fact, the NYAG did not introduce any consumer-perception evidence at all, and there

is no basis in the record to support the jury's findings as to the two Jury Verdict Claims for which the jury found liability under the GBL.

Second, the NYAG failed to introduce any evidence that any of the Challenged Claims were misleading to a reasonable consumer acting reasonably under the circumstances, as required under the GBL. It is shocking that in a trial concerning whether advertisements were allegedly false or deceptive, the NYAG did not offer any witnesses to testify about the Challenged Claims. Nor did it present a single consumer to testify about how he or she interpreted the challenged advertisements for Prevagen. Indeed, none of the NYAG's hired expert witnesses had even reviewed any of Prevagen's advertisements. It is impossible for a plaintiff to prove advertising claims are false, deceptive, misleading or unsubstantiated when it offers no evidence in support of its conclusory assertions to that effect or any evidence of the impression that the advertising conveyed to consumers.

Third, when the NYAG's expert witnesses did testify, they confirmed that they had no idea what the competent and reliable scientific evidence standard meant with respect to dietary supplement advertising. Instead, they appeared to attribute some unknown never-before-announced standard to Defendants' advertising. But their attempt to impose new or heightened standards for the first time during litigation violates Defendants' due process rights. The trial confirmed that is exactly what the NYAG tried to do here.

Fourth, the NYAG failed to rebut the testimony of Defendants' expert that the addition of Vitamin D to Prevagen's formulation satisfies the competent and reliable scientific evidence standard with respect to the Challenged Claims. Accordingly, the jury verdict should apply only to the Prevagen product as it existed prior to Vitamin D being added to the formulation—i.e., prior to 2016 (and prior to the filing of the Complaint).

Finally, Defendants are entitled to judgment as a matter of law on the NYAG's Executive Law claim for the reasons set forth above for all Challenged Claims and because the jury's answers to the questions posed in Charge 3 not related to a Jury Verdict Claim were irrelevant. As the Court instructed the jury, Defendants faced no liability for claims that the jury found did not violate the GBL because the New York Executive Law does not provide a standalone cause of action.

For these reasons and, the reasons set forth more fully in Defendants' summary judgment briefing, it is clear from the trial record that the NYAG failed to prove its case and Defendants are entitled to judgment as a matter of law on all counts.

II. LEGAL STANDARD

Federal Rule of Civil Procedure 50(b) provides that a party may file a renewed motion for judgment as a matter of law following trial if the Court has not yet granted a prior motion made under Rule 50(a). Fed. R. Civ. P 50(b). In ruling on the renewed motion, the Court may direct entry of judgment as a matter of law in favor of the movant. *Id.* "To warrant post-verdict judgment as a matter of law, the movant must show that the evidence, when viewed most favorably to the non-movant, was insufficient to permit a reasonable juror to have found in the non-movant's favor." *Conte v. Emmons*, 895 F.3d 168, 171 (2d Cir. 2018). The moving party must show "a complete absence of evidence supporting the verdict [such] that the jury's findings could only have been the result of sheer surmise and conjecture, or ... such an overwhelming amount of evidence in favor of the movant that reasonable and fair minded [persons] could not arrive at a verdict against [it]." *Song v. Ives Lab'ys, Inc.*, 957 F.2d 1041, 1046 (2d Cir. 1992) (citing *Mattivi v. South African Marine Corp.*, 618 F.2d 163, 168 (2d Cir. 1980)).

III. ARGUMENT

A. The NYAG Did Not Meet Its Burden To Prove The Challenged Claims Were Even Made, Let Alone That They Were Misleading

To succeed on its claims under the GBL Sections 349 and 350, the NYAG was required to prove, by a preponderance of the evidence, that for *each* of the Challenged Claims, Defendants "engaged in (1) consumer-oriented conduct that is (2) materially misleading and that (3) plaintiff suffered injury as a result of the allegedly deceptive act or practice." *Koch v. Acker, Merrall & Condit Co.*, 18 N.Y.3d 940, 941 (2012) (citation omitted). Because "[m]ateriality under [the GBL] is an objective inquiry; a deceptive act is defined as one 'likely to mislead a reasonable consumer acting reasonably under the circumstances.'" *In re KIND LLC "Healthy and All Natural" Litig.*, 627 F. Supp. 3d 269, 280 (S.D.N.Y. 2022) (quoting *Maurizio v. Goldsmith*, 230 F.3d 518, 521–22 (2d Cir. 2000)). In light of this objective inquiry, a plaintiff's "own conclusory allegations" and "anecdotal testimony" to show what implied claims are conveyed by an advertisement is "plainly insufficient." *Hughes v. Ester C Co.*, 330 F. Supp. 3d 862, 872 (E.D.N.Y. 2018) (internal quotation marks omitted). Rather, "[t]o satisfy the reasonable consumer standard, a plaintiff must adduce extrinsic evidence . . . to show how reasonable consumers interpret the challenged claims." *In re KIND LLC "Healthy and All Natural" Litig.*, 627 F. Supp. 3d at 282 (quoting *Hughes*, 330 F. Supp. 3d at 872).

After hearing all of the evidence at trial, the jury found that six of the eight Challenged Claims did not violate the GBL: (1) "Prevagen improves memory"; (2) "Prevagen is clinically shown to improve memory"; (3) "Prevagen improves memory within 90 days"; (4) "Prevagen is clinically shown to improve memory within 90 days"; (5) "Prevagen provides other cognitive benefits, including but not limited to healthy brain function, a sharper mind, and clearer thinking";

and (6) "Prevagen is clinically shown to provide other cognitive benefits, including but not limited to healthy brain function, a sharper mind, and clearer thinking." (*See* Dkt. No. 421 at pp. 2–3, 5.)

Despite correctly finding that the primary marketing claims for Prevagen did not violate the GBL, the jury found that the NYAG satisfied its burden with respect to only two of the eight Challenged Claims, namely: (1) "Prevagen reduces memory problems associated with aging"; and (2) "Prevagen is clinically shown to reduce memory problems associated with aging." *Id.* However, these alleged Jury Verdict Claims do not appear anywhere in the trial transcript (except in attorney argument) nor do they appear in any of the marketing material admitted into evidence. In other words, the NYAG failed to introduce any evidence of the Defendants making these two claims to the Court or jury. Accordingly, to the extent that the jury concluded that these two claims were conveyed, that conclusion lacked any evidentiary support, warranting judgment as a matter of law in Defendants' favor.

Alternatively, Defendants are still entitled to judgment as a matter of law even if the Jury Verdict Claims are considered "implied" because the NYAG failed to provide any consumer perception evidence to the jury. The NYAG's failure to provide such consumer perception evidence, in light of the fact that neither express statement is found in any advertisement in evidence, or even mentioned at trial other than in attorney argument, is a failure of proof on its claims.

Courts in this Circuit routinely hold that when plaintiffs asserting claims under the GBL challenge implied advertising claims (i.e., advertising claims that are made indirectly or by inference), they must present evidence that reasonable consumers interpret the challenged advertising in the same manner alleged by the plaintiffs. For example, in *Colangelo v. Champion Petfoods USA, Inc.*, the plaintiffs alleged that claims that certain pet foods were "Biologically

Appropriate" were deceptive because the products allegedly contained heavy metals. No. 6:18-cv-1228, 2022 WL 991518, at *19 (N.D.N.Y. Mar. 31, 2022), *aff'd sub nom. Paradowski v. Champion Petfoods USA, Inc.*, No. 22-962, 2023 WL 3829559 (2d Cir. June 6, 2023). The court granted summary judgment for the defendant on the plaintiffs' GBL claims because (like the NYAG) they failed to "provide[] admissible evidence demonstrating that the 'Biologically Appropriate' label would lead a reasonable consumer to believe the products contained no heavy metals or BPA." *Id.* at *21. This Second Circuit affirmed this decision. *See Paradowski v. Champion Petfoods USA, Inc.*, No. 22-962, 2023 WL 3829559 (2d Cir. June 6, 2023).

Similarly, in *de Lacour v. Colgate-Palmolive Co.*, which involved false advertising allegations regarding "natural" toothpaste, the court ruled that "Plaintiffs must offer evidence that could support a finding that a reasonable consumer understands that Tom's use of 'natural' conveys that Tom's products do not contain synthetic and/or highly chemically processed ingredients." No. 1:16-cv-8364, 2024 WL 36820, at *4 (S.D.N.Y. Jan. 3, 2024). Again, this Court granted summary judgment for the defendant on claims brought under the GBL because (like the NYAG here) the plaintiffs "failed to produce evidence that a reasonable consumer interprets [the challenged advertising claim] in the manner Plaintiffs allege". *Id.* at *7.

And in *In re KIND*, this Court ruled that the reasonable consumer standard of the GBL requires proof that "a significant portion of the general consuming public or of targeted consumers, acting reasonably in the circumstances, could be misled." 627 F. Supp. 3d at 282. Accordingly, it fell to the plaintiffs to "'introduce evidence that could support a finding that reasonable consumers believe[d]' the plaintiffs' proffered theory of deception." *Id.* at *282 (quoting *Tran v. Sioux Honey Ass'n, Coop.*, 471 F. Supp. 3d 1019, 1026 (C.D. Cal. 2020)). And to make that showing, this Court required the plaintiffs to "adduce extrinsic evidence—ordinarily in the form

of a survey—to show how reasonable consumers interpret[ed] the challenged claims." *Id.*; *see also Stokely-Van Camp, Inc. v. Coca-Cola Co.*, 646 F. Supp. 2d 510, 525 (S.D.N.Y. 2009) (in Lanham Act case, to establish that an implied claim is misleading, a plaintiff "must offer consumer data or other extrinsic evidence to show that the audience to which the advertisement is directed is in fact misled by the advertisement"); *Naked Cowboy v. CBS*, 844 F. Supp. 2d 510, 518 (S.D.N.Y. 2012) (GBL §§ 349 and 350 standards are the same as those applied to claims brought under Lanham Act).

Undeterred by this caselaw, the NYAG failed to introduce any consumer perception evidence at trial that would establish what the advertisements introduced into evidence conveyed to consumers. The NYAG also failed to introduce evidence showing that consumers did, in fact, interpret the advertisements in the record as the Challenged Claims. Given the glaring absence of evidence—including, more specifically, evidence regarding the two Challenged Claims the jury found to violate GBL 349 and 350—the NYAG failed to offer proof to support the jury's verdict. As such, no reasonable juror could have concluded that the Jury Verdict Claims were made or that they were materially misleading. The jury's findings with respect to these claims were the "result of sheer surmise and conjecture" and warrants judgment as a matter of law for the Defendants. *Song*, 957 F.2d at 1046.

B. The NYAG Failed To Introduce Any Evidence Establishing That The Challenged Claims Were Unsubstantiated Or Deceptive

Defendants are independently entitled to judgment as a matter of law because the NYAG failed to put forth any evidence to suggest that any of the Challenged Claims were false, deceptive, or unsubstantiated. As discussed above, the NYAG was required to prove that the Challenged Claims were "likely to mislead consumers acting reasonably under the circumstances." *In re KIND LLC "Healthy and All Natural" Litig.*, 627 F. Supp. 3d at 280. To succeed on a false advertising

trial, a plaintiff has the burden to prove that the challenged claims were false or misleading. *See People v. Gen Electric Co.*, 302 A.D.2d 314, 315 (1st Dep't 2003) ("the plaintiff must prove that the challenged act or practice was misleading in a material way and the deceptive practice must be likely to mislead a reasonable consumer acting reasonably under the circumstances") (internal citations omitted); *see also* Trial Tr. at 1445:23–25 ("it's the Attorney General's burden to prove, by a preponderance of the evidence, that Quincy's proffered support is not competent and reliable evidence"). The NYAG failed to do so. The NYAG presented no evidence whatsoever that any of the Challenged Claims would mislead a consumer. The NYAG did not call a single fact witness to testify on its own behalf. And *none* of the NYAG's experts offered any opinion on the Challenged Claims. Indeed, *none* of the NYAG's witnesses were even familiar with or could identify the Challenged Claims. To the contrary, Quincy's expert witnesses testified that the science supported the Challenged Claims. It is axiomatic that in order to succeed on a false advertising trial, a plaintiff must introduce some evidence that the advertising being challenged were false or misleading. The NYAG failed to do so, and in the face of Quincy's unrebutted witness testimony, no reasonable juror could have found in the NYAG's favor on any claim. Judgment as a matter of law should therefore be granted in Defendants' favor. *See, e.g., Karibian v. Columbia Univ.*, 930 F. Supp. 134, 150 (S.D.N.Y. 1996) (granting motion for judgment as a matter of law "because there was no reasonable basis in the evidence to support the jury's verdict.").

For example, the NYAG's expert Dr. Sano confirmed during her trial testimony that she did not review any of Prevagen's labels or advertising before writing her expert reports. (Trial Tr. at 299:20–22; 300:7–9.) Dr. Sano further confirmed that she was not even aware of what claims the NYAG was challenging in this action. (*Id.* at 300:13–15). She also confirmed that she was

not offering an opinion whatsoever about the marketing claims for Prevagen. (*Id. at* 300:16–18; 300:24–301:1.)

Similarly, the NYAG's expert Dr. Wittes confirmed that she did not know what any of the Challenged Claims were because she did not review any advertising for Prevagen, (*id.* at 483:21–24), did not review any Prevagen labels (*id.* at 483:25–484:2), and did not review the Complaint filed in this action. (*Id.* at 484:4–7.) Dr. Wittes further confirmed that she has never performed any work to determine whether any evidence supports an advertising claim, (*id.* at 490:9–12; 490:18–22), and that she "do[es]n't know anything about the relationship between the science and the advertising claims." (*Id.* at 494:13–14.)

And the NYAG's expert Dr. Berg offered no opinion or testimony about any claim made in Prevagen advertising, but instead discussed his flawed view of *one* way Prevagen *might* work. (*Id.* at 619:15–17; 622:3–6.) Dr. Berg's testimony had nothing to do with whether any advertisement could or actually did mislead a consumer acting reasonably under the circumstances.

On the other hand, Quincy's experts testified specifically about the claims being challenged in this action, and opined that the claims made in Prevagen advertising are supported by competent and reliable scientific evidence. For example, Dr. David Katz, the only medical doctor to testify at trial, reviewed the science amassed by Defendants and concluded that all of the advertising claims are supported by competent and reliable scientific evidence. (*Id.* at 1259:3–19; 1260:3–1261:18; *see also id.* at 1320:13–15 (The Court: "Did the study support the statements made in the claims, in your opinion?" Dr. Katz: "Yes, your Honor.").) Likewise, Dr. Mindy Kurzer, an expert in nutritional science, dietary supplements and biostatistics, testified that the scientific evidence that she reviewed provides competent and reliable scientific evidence to support the claims made in Prevagen advertising. (*Id.* at 980:6–15.) Dr. Dominik Alexander, an

epidemiologist, reviewed the Madison Memory Study methodology to determine if that randomized clinical trial ("RCT") *alone* was sufficient competent and reliable scientific evidence to support the advertising claims. He determined that it was. (*Id.* at 1064:13–1065:9; 1081:1–4.) Perhaps most importantly, Dr. David Schwartz—a neuroscientist and the only expert in dietary supplement claim substantiation to testify at the trial—testified that the advertising claims were supported by competent and reliable scientific evidence. (*Id.* at 1119:1–5; 1123:4–11; 1124:5–12; 1126:17–21; 1129:20–1130:8; 1154:10–16.)

In other words, Defendants' experts, all of whom are experts in the relevant scientific fields, reviewed the actual advertising claims being challenged, and found them to be substantiated. *See United States v. Bayer Corp.*, No. 07-01, 2015 WL 5822595, at *14 (D.N.J. Sept. 24, 2015) ("Because the definition of 'competent and reliable scientific evidence' looks to the view of experts in the relevant field, it is appropriate for the Court to consider the testimony of experts in the field."); (*see also* Trial Ex., DX-526 at 9–18.)

The NYAG failed to meet its burden: its witnesses did not consider the claims made in Prevagen advertising and did not opine whether the Challenged Claims, as they appeared in context, were adequately substantiated. The NYAG also failed to meet its burden to prove that the Challenged Claims, as they appeared in Prevagen advertising, were likely to mislead a consumer acting reasonably under the circumstances. *See People v. Gen Electric Co.*, 302 A.D.2d at 315 ("the plaintiff must prove that the challenged act or practice was misleading in a material way and the deceptive practice must be likely to mislead a reasonable consumer acting reasonably under the circumstances"); (*see also* Trial Tr. 1445:23–25 ("it's the Attorney General's burden to prove, by a preponderance of the evidence, that Quincy's proffered support is not competent and reliable evidence").) The NYAG utterly failed to introduce any evidence that the claims made in Prevagen

advertising were likely to mislead anyone. In the face of Quincy's unrebutted witness testimony that the science did support the Challenged Claims, no reasonable juror could have found in favor of the NYAG on any claim. Judgment as a matter of law should therefore be granted in Defendants' favor. *See, e.g.*, *Karibian*, 930 F. Supp. at 150 (granting motion for judgment as a matter of law "because there was no reasonable basis in the evidence to support the jury's verdict.").

C. The NYAG's Witnesses Erroneously Subjected The Challenged Claims To A Higher Substantiation Standard Than The Law Permits For Dietary Supplement Products Like Prevagen

Defendants are also entitled to judgment as a matter of law because, as the trial testimony made clear, the NYAG seeks to hold Defendants to a higher substantiation standard than what the law requires as competent and reliable scientific evidence to substantiate a dietary supplement marketing claim. This is a violation of Defendants' due process rights. As this Court instructed the jury:

> Competent and [reliable] [sic] scientific evidence means tests, analyses, research, studies, or other evidence, based on the experts of professionals in a relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do to, using procedures generally accepted in the profession to yield accurate and reliable results.
>
> You should look to what experts in the field would consider to be adequate in determining the amount and type of evidence that's sufficient to demonstrate a Prevagen claim is supported. There's no fixed formula for determining what constitutes competent and reliable scientific evidence. It's a flexible standard that may consider all forms of scientific evidence, including human, clinical trials, animal studies, in vitro studies, scientific literature, expert opinions, and other scientific studies.

(Trial Tr. at 1445:7–21.)*; see also Bayer*, 2015 WL 5822595, at *3–4 ("'competent and reliable scientific evidence' is a 'flexible' standard, and '[t]here is no fixed formula for the number or type of studies required;" RCTs "are not necessary"; "animal and in vitro studies will also be

examined;" "'[e]pidemiologic evidence may be an acceptable substitute for clinical data' in some circumstances;" "one should look to 'the totality of the evidence'"); (Trial Ex., DX-526 at 9–18.)

The NYAG's experts conceded at trial that they had never even heard of the phrase "competent and reliable scientific evidence" when forming their opinions in this case and that they instead applied their own made-up standards in evaluating Defendants' substantiation. (Trial Tr. at 497:2–6; 497:16–24) (Dr. Wittes admitted she never heard the phrase "competent and reliable scientific evidence" and did not know what it meant); *id.* at 302:8–305:14) (Dr. Sano admitted she did not know the dietary supplement advertising guide's definition of "competent and reliable scientific evidence" and opined that a higher substantiation standard is required for claims relating to memory or cognition). The trial record is clear that the NYAG, through its witnesses, attempted to impose a different, *higher* standard for Defendants to satisfy, instead of the competent and reliable scientific evidence standard that governs this case.

Because the NYAG's experts' critiques of the Madison Memory Study were lodged under this heightened and inappropriate standard, they do not support judgment in the NYAG's favor on any claim, including the two Jury Verdict Claims that the jury found to be misleading. In any event, the testimony and evidence submitted to the jury irrefutably established that the Madison Memory Study satisfied all of the hallmarks of an RCT and provided adequate substantiation for the Challenged Claims (even though an RCT is not required). Indeed, Dr. Sano and Dr. Wittes, the NYAG's own experts, both conceded that the Madison Memory Study was a randomized, placebo controlled clinical trial. (*Id.* at 276:4–13; 500:15–24.) Dr. Wittes further testified that when she analyzed the data, she reached the same results as the Madison Memory Study researchers—namely, that the people in the AD8 0-1 and 0-2 groups who took Prevagen outperformed those in the placebo on 16 out of 18 measurements. (Trial Tr. at 511:1–15; 512:16–

513:4); *id.* at 508:15–21) (Dr. Wittes admitting she is not challenging the data from the Madison Memory Study nor contending that the data is in any way made up or flawed). In other words, trial testimony confirmed that the NYAG's criticisms of the Madison Memory Study were pure speculation not grounded in any factual basis.

As another example, the NYAG put on no evidence to support its main criticisms that the Madison Memory Study's analyses were unplanned from the outset, or "post hoc" as the NYAG coined it. The NYAG's experts simply assumed that incorrect so-called "fact."

To the contrary, all of Defendants' fact witnesses testified that the data for individuals within Prevagen's target population—those with AD8 scores between 0 and 2, representing generally healthy, older individuals with memory concerns associated with the normal aging process—was the first data from the Madison Memory Study that was analyzed and it was always intended to be analyzed first. (*See id.* at 262:21–24 (trial testimony of Kenneth Lerner stating the 0-1 and 0-2 groups were the first three analyzed); *id.* at 92:2–7 (trial testimony of Todd Olson stating "the people that we're talking about, which was our target market, the intended study population"); *id.* at 825:7–13 (trial testimony of Mark Underwood discussing benefits shown in those in the Madison Memory Study with AD8 scores of 0-2).

Moreover, the NYAG's witnesses confirmed during trial that the NYAG's "post hoc" theory—to the extent it should be given any credence whatsoever (it should not)—was purely theoretical. (*See id.* at 517:12–14) (Q: "You don't know the sequence of how the [Madison Memory Study] data was analyzed, right?" Dr. Wittes: "That's correct"); *id.* at 321:12–18) (Dr. Sano admitting she does not know when any subgroup analyses was planned or conducted)[1].

[1] Dr. Berg did not offer any opinions at all about the Madison Memory Study. (Trial Tr. at 681:2–5.)

The NYAG's attempt to hold Defendants to a different, higher and never-before-announced competent and reliable scientific evidence standard violates Defendants' due process rights. *See, e.g., Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 158–59 (2012) ("It is one thing to expect regulated parties to conform their conduct to an agency's interpretations once the agency announces them; it is quite another to require regulated parties to divine the agency's interpretations in advance or else be held liable when the agency announces its interpretations for the first time in an enforcement proceeding and demands deference"); *NLRB v. Majestic Weaving, Co.*, 355 F.2d 854, 860 (2d Cir. 1966) ("a decision branding as 'unfair' conduct stamped 'fair' at the time a party acted, raises judicial hackles" where the conduct "might even have been taken in express reliance on the standard previously established"); *Stroller v. Commodity Futures Trading Comm'n*, 834 F.2d 262, 267 (2d Cir. 1987) (reversing agency order that "abruptly changed [the agency's] interpretation in the middle of proceedings.") Defendants are entitled to judgment as a matter of law on all counts because the NYAG's never-before-announced competent and reliable scientific evidence standard violated Defendants' due process rights.

D. The NYAG Failed To Offer Any Evidence To Rebut Dr. Kurzer's Testimony That The Challenged Claims Are Substantiated By Research Involving Vitamin D

In addition to the failures of proof discussed above, the NYAG failed to offer any evidence to contradict Dr. Kurzer's testimony that there is competent and reliable scientific evidence that Vitamin D (which was added to Prevagen in 2016) supports the Challenged Claims. Defendants, therefore, are entitled to judgment as a matter of law on all counts for this additional reason.

At trial, Dr. Kurzer testified that she conducted a literature search and reviewed 86 peer-reviewed studies involving the relationship between Vitamin D and cognitive function. (Trial Tr. at 1007:7–10, 1008:9–13, 1009:21–1010:6.) Dr. Kurzer testified that 76% of the epidemiological cross-sectional studies that she reviewed showed a beneficial association between Vitamin D and

cognitive function. (*Id.* at 1010:10–20.) Dr. Kurzer further testified that these cross-sectional studies constitute competent and reliable scientific evidence for the Challenged Claims. (*Id.* at 1010:21–24.) Dr. Kurzer also testified that 73% of the epidemiological prospective studies that she reviewed—studies in which people were observed over a number of years—showed a beneficial association between Vitamin D and cognitive function. (*Id.* at 1010:25–1011:24.) Dr. Kurzer testified that these studies constituted competent and reliable evidence in support of the Challenged Claims. (*Id.* at 1011:25–1012:3.) Finally, Dr. Kurzer testified that all twelve of the meta-analyses—a specific statistical technique used by researchers to combine a number of studies together—that she reviewed showed a beneficial relationship between Vitamin D and cognitive function (*Id.* at 1011:2–24; 1014:11–1015:1.) These additional Vitamin D studies, according to Dr. Kurzer, constitute competent and reliable scientific evidence that the Challenged Claims are substantiated. (*Id.* at 1011:25–1012:3; 1015:6-16.)

The NYAG failed to rebut Dr. Kurzer's expert testimony. Rather, the NYAG offered only Dr. Sano to discuss Vitamin D. Dr. Sano, however, admitted that she was not an expert in Vitamin D and made clear that her testimony with respect to Vitamin D was subject to a "a qualification" that she only "talk[ed] about [the] general public without talking about a Vitamin D deficient population" as a whole. (*Id.* at 321:24–25; 322:1–323:3.) The uncontroverted evidence at trial, though, is that roughly half of the American population is deficient in Vitamin D, and certain subgroups, such as African Americans (80%) and Hispanic Americans (70%) have an even higher Vitamin D deficiency. (*Id.*at 1007:12–1008:8.) Dr. Sano ignored this evidence, and instead *qualified* her opinion to apply only to the percentage of Americans who are *not* Vitamin D deficient. As the NYAG failed to provide any evidence to rebut Dr. Kurzer's comprehensive testimony regarding the interplay between Vitamin D and cognitive health, the NYAG failed to

meet its burden of proof with respect to all Challenged Claims following the addition of Vitamin D to Prevagen in 2016 and Defendants are entitled to judgment as a matter of law on those claims.

E. Defendants Are Entitled To Judgment As A Matter Of Law On the Executive Law Claim

Finally, because the NYAG has failed to prove its claim under the GBL with respect to each of the Challenged Claims, Defendants are also entitled to judgment as a matter of law on the NYAG's claims under the New York Executive Law 63(12). As this Court already held, there is no separate independent cause of action under New York Executive Law 63(12) and those claims rise or fall with the NYAG's GBL claims.

The Court was clear in its instruction to the jury that there is no independent cause of action for the New York Executive Law:

> If you do not find the Quincy defendants libel [sic] under the general business law sections, then you do not need to reach the Attorney General's charge under the New York Executive Law because, in effect, that charge has already been disposed of. If, however, you find that one or more of the Quincy defendants violated the general business law, then you will decide the executive law section.

(Trial Tr. at 1447:21–1448:2.) Thus, the jury did not need to reach the Executive Law charge with respect to any Challenged Claim for which it found no GBL liability because there is no standalone cause of action under the Executive Law. *See, e.g.*, *People ex rel. Schneiderman v. One Source Networking, Inc.*, 125 A.D.3d 1354, 1355–56 (4th Dep't 2015) (Section 63(12) "does not create an independent cause of action" but rather "is only a mechanism by which a petitioner may show that injunctive relief and restitution are proper in the event that the petitioner establishes that a respondent violated other statutes"); *see also People ex. Rel. Spitzer v. Frink Am., Inc.*, 2 A.D.3d 1379, 1380 (4th Dep't 2003); *City of New York v. FedEx Ground Package System, Inc.*, 175 F. Supp. 3d 351, 363–64 (S.D.N.Y. 2016) (finding 63(12) claim fails where underlying cause is not

adequately pled; state cannot get civil penalties under 63(12) absent ability to collect penalties from underlying statute).

Accordingly, Defendants submit that the Court should set aside the jury's answers to Charge 3 with respect to all Challenged Claims—but at a minimum with respect to the six Challenged Claims that the jury found did not violate the GBL—and enter judgment as a matter of law in Defendants' favor on the NYAG's New York Executive Law 63(12) claim. *See Karibian,* 930 F. Supp. at 150 (granting judgment as a matter of law on jury questions that were irrelevant to the issue of liability for a claim).

IV. CONCLUSION

For the foregoing reasons, Defendants respectfully request that this Court grant Defendants' renewed motion for judgment as a matter of law and grant judgment in favor of Defendants on all counts.

Date: April 8, 2024

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